REMARKS

As a result of the foregoing amendments, claims 1-19, 21-33, 35 and 43 have been canceled and claims 20, 34, 36-42 and 44-46 have been amended. A substitute specification and abstract have been provided. The title of the specification has been amended. A proper priority application paragraph has been added to the substitute specification. Process claim 20 reads on withdrawn Group II from the election requirement of March 17, 2004. Claims 34, 36-42 and 44-46 are pending.

No new matter has been added by these amendments. Withdrawn claim 20 has been amended to change its dependency from canceled claim 13 to pending claim 39. Claims 34, 36-42 and 44-46 have been amended to remove typographical errors, clarify their language, provide proper antecedent basis for terms and limit the encoded enzymes to those of the species disclosed in the specification in paragraph 0092.

Applicants respectfully request reconsideration and withdrawal of all pending objections and rejections.

Objections to Drawings, Abstract, Specification and Title have been Overcome

As a result of the foregoing amendment to the abstract and entry of the substitute specification all objections to the drawings, abstract, specification, priority claim and title have been overcome. Reconsideration and withdrawal of these objections are respectfully requested.

35 USC §112, Second Paragraph Rejections Overcome by Amendment

Claims 1-3, 5-7, 13-18, 25-29, 31, 39-41 and 45-46 stood rejected as being indefinite under 35 USC §112, second paragraph, as described in paragraphs [a] through [f] as found on pages 5 and 6 of the Office Action. The rejections of paragraphs [a] through [d] are moot, because they reject now-canceled claims. The rejections of paragraphs [e] and [f], for lack of antecedent basis and improper dependency, respectively, have been overcome by the amendment to claims 39, 45 and 46, as suggested by the Examiner.

35 USC §112, First Paragraph Rejections Improper

Claims 1-8, 13-18, 25-29, 31 and 33-46 stood rejected under 35 USC §112, second paragraph, for an alleged failure to comply with the written description requirement. The rejection

of now-canceled claims 1-8, 13-18, 25-29, 31, 33, 35 and 43 is moot. Reconsideration and withdrawal of the rejection of claims 34, 36-42 and 44-46 are respectfully requested. On pages 7-9, the Office Action argues that the genus claimed is broader than that described by the specification. All pending claims are limited to expression cassettes comprising heterologous DNAs of specific enzymes selected from a limited number of species. The specification teaches in paragraph 0092 the limited number species which may be sources for heterologous DNAs of cholesterol to hydrocortisone pathway enzymes used in the instant invention. The specification, particularly the examples, contains many examples of these heterologous DNAs from several species. The specification also teaches a method of obtaining any heterologous DNA used in the instant invention from that limited number of species. See paragraphs 0092 to 0105. Regarding the undue breadth asserted by the Office Action to the phrase "progeny thereof" when referring to recombinant host cells, this phrase has been removed from the pending claims. Accordingly, the rejection for lack of written description should be withdrawn.

Claims 1-8, 13-18, 25-29, 31 and 33-46 stood rejected under 35 USC §112, second paragraph, for an alleged lack of enablement. The rejection of now-canceled claims 1-8, 13-18, 25-29, 31, 33, 35 and 43 is moot. Reconsideration and withdrawal of the rejection of claims 34, 36-42 and 44-46 are respectfully requested. On pages 9-14, the Office Action argues that the genus claimed is broader than that enabled by the specification. All pending claims are limited to expression cassettes comprising heterologous DNAs of specific enzymes selected from a limited number of species. The specification teaches in paragraph 0092 the limited number species which may be sources for heterologous DNAs of cholesterol to hydrocortisone pathway enzymes used in the instant invention. The specification, particularly the examples, contains many examples of these heterologous DNAs from several species. Any molecular biologist of ordinary skill in that art would be able to isolate each heterologous DNA encoding for use in the instant invention by following the directions of paragraphs 0092 to 0105 of the specification. Accordingly, the rejection for lack of enablement should be withdrawn.

Claims 9-12 stood rejected under 35 USC §112, second paragraph, for an alleged lack of enablement. This rejection of now-canceled claims 9-12 is moot.

Double-Patenting Rejections Should be Withdrawn

The provisional double-patenting rejection under 35 USC §101 is moot, as only now-canceled claims stood provisionally rejected.

The various judicially-created doctrine of obviousness-type double patenting rejections and provisional judicially-created doctrine of obviousness-type double patenting rejections found on pages 16-18 should be withdrawn. These rejections and provisional rejections are either moot due to cancellation of claims or have been overcome by the above amendments. None of US Patents 5,869,283 6,171,836 or US Application 10/462,128 contain claims which make obvious the particular requirements of the pending claims for a specific combination of enzymes encoded in an expression cassette.

Instant Application is Fully Entitled to Earliest Claimed Priority Date of May 6, 1988

On page 19 of the Office Action, this Application is incorrectly denied the full benefit of its foreign priority claim. This error appears to stem from use of an incorrect PCT application in the Office Action's analysis. The earliest filed U.S. non-provisional application on which this application claims priority is 07/474,798, filed July 16, 1990. This U.S. non-provisional was timely filed (within the allowable time for nationally filing an international application) to properly claim priority on PCT/NL89/00032 (not PCT/NL89/00072, as stated in the Office Action). PCT/NL89/00032 was filed Monday, May 8, 1989 and designated the U.S. Accordingly, the earliest U.S. filing date of the instant application is the filing date of PCT/NL89/00032, May 8, 1989.

Furthermore, the instant application properly claims foreign priority dates of May 6, 1988 and September 23, 1988. These are the filing dates of two European Patent Applications (NL 88200904.6 and NL88202080.3, respectively), from which priority was properly claimed in the filing of PCT/NL89/00032 on Monday, May 8, 1989. A copy of the front page of PCT/NL89/00032 is attached, showing the proper priority claims.

Anticipation Rejection is Moot

All the claims that stood rejected under 35 U.S.C. §102 have been canceled. Accordingly, this rejection is moot.

Obviousness Rejections Should Be Withdrawn

The Office Action fails to state a prima facie case of obviousness, because all the rejections under 35 USC §103 rely on Sadlaczek et al (Crit Rev Biotechnol 7:187-236), and Sadlaczek et al was never evaluated to determine whether it is a proper reference against the instant application. The Office Action contains no allegation or suggestion that Sadlaczek is a proper §102(b) reference (i.e. was published more than one year before the correct U.S. priority date of May 8, 1989) or a proper §102(e) reference (i.e. was published before the earliest foreign priority date of May 6, 1988). Accordingly, these obviousness rejections should be reconsidered and withdrawn.

These obviousness rejections should also be reconsidered and withdrawn because the cited prior art, alone or in combination, fails to teach or suggest the limitations of the instant claims of specific combinations of multiple specific enzymes encoded in the same expression cassette.

Applicants respectfully submit that the application is now in condition for allowance and request prompt notice thereof.

Respectfully submitted,

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